IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO

STEPHANIE WYSKOCIL, *Administrator of the Estate of Robert Wyskocil, Deceased*,	**Case No. 1:24-cv-01697-PAB**
Plaintiff,	**JUDGE PAMELA A. BARKER**
-vs-	
MEDTRONIC USA, INC., et al.,	**MEMORANDUM OPINION AND ORDER**
Defendants.	

Currently pending before this Court is Defendants Medtronic USA, Inc., Medtronic, Inc., and Medtronic, Inc. dba Covidien's (collectively "Defendants" or "Medtronic") Motion to Dismiss filed on October 10, 2024 ("Defendants' Motion"). (Doc. No. 7.) On December 19, 2024, Plaintiff filed her Opposition to Defendants' Motion ("Plaintiff's Opposition"). (Doc. No. 9.) On January 2, 2025, Defendants filed their Reply in support of Defendants' Motion ("Defendants' Reply"). (Doc. No. 10.) Accordingly, Defendants' Motion is ripe for a decision.

For the reasons set forth herein, the Court GRANTS IN PART and DENIES IN PART Defendants' Motion.

I. Background

Plaintiff's Complaint sets forth the following allegations.[1]

Defendants "are and were at all times pertinent hereto, corporations and/or other business entities organized or existing under the laws of the State of Minnesota and/or were licensed and/or

[1] For purposes of this Opinion, in setting forth the background relevant to Defendants' Motion to Dismiss, the Court accepts Plaintiff's factual allegations as true and construes her Complaint in the light most favorable to her as the non-moving party. *See Gunasekera v. Irwin*, 551 F.3d 461, 466 (6th Cir. 2009).

were doing business in the State of Ohio, and/or regularly did or solicited business, or engaged in other persistent courses of conduct or derived substantial revenue from goods used or consumed or services rendered in the State of Ohio." (Doc. No. 1-1 at ¶ 4.) Plaintiff Stephanie Wyskocil is the duly appointed, qualified and acting Administrator of the Estate of Robert Wyskocil, Deceased (hereinafter "Decedent"). (*Id.* at ¶ 1.) Plaintiff brings this action for the exclusive benefit of the next-of-kin of Decedent. (*Id.* at ¶ 2.)

On and before September 12, 2020, Decedent was a patient at Western Reserve Hospital (hereinafter the "Hospital") and was "being intubated with a Covidien endotracheal tube (ETT), which tube's cuff failed [sic] causing an air leak, improper ventilation and oxygen desaturation." (*Id.* at ¶ 3.) Based upon information and belief, Plaintiff alleges that "said ETT was designed, manufactured and sold by the [Defendants]." (*Id.*) "During said medical care, two more of [D]efendants' ETT's were employed and failed." (*Id.*) "Specifically, ETT No. 3 immediately experienced a catastrophic failure at the cuff and before a fourth ETT could be employed, [D]ecedent expired due to oxygen desaturation." (*Id.*)

Attached as Exhibit B to Plaintiff's Complaint is a Discharge Summary dated 09/12/2020 from the Hospital that reads as follows:[2]

> "Early in the morning of 9/12/2020[,] the patient's endotracheal tube (ETT) cuff failed, causing an air leak, improper ventilation and oxygen desaturation observable on telemetry.

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[2] "The law is clear that courts may consider a document which was attached to the complaint in determining whether dismissal is proper." *DG Gas, LLC v. TA Franchise Systems LLC*, 2025 WL 814928, at *5 n.6 (N.D. Ohio Mar. 14, 2025) (citing *Cates v. Crystal Clear Technologies, LLC*, 874 F.3d 530, 536 (6th Cir. 2017)); *Detrick v. KCS International Inc.*, 2025 WL 1133516, at *38 (N.D. Ohio Apr. 17, 2025) (citing Fed. R. Civ. P. 10(c)) ("[A] copy of any written instrument that is an exhibit to a pleading is part of the pleading for all purposes."). Because Plaintiff refers to the medical records in her Complaint and the records are central to her claims, the Court may consider those records. *See Bassett v. Nat'l Collegiate Athletic Ass'n*, 528 F.3d 426, 460 (6th Cir. 2008) ("When a court is presented with a Rule 12(b)(6) motion, it may consider the Complaint and *any exhibits attached thereto* … so long as they are referred to in the Complaint and are central to the claims contained therein.").

> The decision was made to make an ETT exchange over bougie. The exchange went well and without incident. Throughout that morning[,] two more patients intubated with COVIDIEN ETTs experienced cuff failure requiring exchange over bougie. Finally[,] at approximately 0700[,] ETT #2s cuff failed, once again necessitating exchange to resume appropriate ventilation[.] A replacement ETT (#3) was tested per protocol to ensure all components were functioning, including the cuff which inflated and deflated properly. A bougie was placed into ETT #2 to approximately half the length of the bougie[.] ETT #2 was removed over the bougie, and the replacement (#3) was threaded over the bougie to the previously recorded depth at the teeth. The cuff was inflated and ventilation was attempted without success: ETT #3 immediately experienced a catastrophic failure at the cuff.
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> ETT #4 was tested and prepared, once again ensuring the cuff was functioning. Prior to attempting an exchange, however, the patient's oxygen saturation fell to critical levels requiring emergent bag valve mask ventilation. To achieve an adequate seal, the bougie had to be forfeited. De novo intubation with ETT #4 was then attempted using a GlideScope to visualize the airway. Traumatic edema made intubation impossible, however. An attempt at passing a bougie through the vocal cords was attempted but also unsuccessful. At this point the patient had gone into cardiac arrest from hypoxia and CPR was initiated. Code blue was called and ACLS was run for approximately 15 cycles (45 minutes)[.] During this time[,] surgical and ENT residents at bedside were called upon for an emergency airway. Tracheostomy was attempted approximately 3 times, but was complicated by body habitus. Ultimately when an emergent airway had been established the patient had lost all cardiac electrical activity as confirmed by telemetry and cardiac ultrasonography. Patient was pronounced dead at 0905. Daughter was present in family waiting room at time of death and was notified immediately. All post-mortem protocol was completed and cross checked by senior nursing staff."

(Doc. No. 1-1 at PageID #15.)

According to Plaintiff, "at all times pertinent hereto, [Defendants] were the manufacturers of the products referenced … above, as that term is defined under OHIO REV. CODE STAT. ANN. § 2307.71(I)." (Compl. at ¶ 10.) Plaintiff alleges that "[a]s a direct and proximate result of the [D]efendants' defective products, [Decedent] died on September 12, 2020." (Compl. at ¶ 5.) Plaintiff claims various damages "against [D]efendants, jointly and severally, on behalf of the next-of-kin, for the wrongful death of [Decedent] …" (Compl. at PageID #10.)

In her Complaint, Plaintiff asserts four different violations of Ohio product liability statutes. Specifically, Plaintiff alleges that "the products as manufactured by [Defendants] were defective in

manufacture and construction as described in OHIO REV. CODE STAT. ANN. § 2307.74, were defective in design or formulation as described in OHIO REV. CODE STAT. ANN. § 2307.75, were defective due to inadequate warnings and instructions as described in OHIO REV. CODE STAT. ANN. § 2307.76, and were defective because they did not confirm to representations made by their manufacturers as described in OHIO REV. CODE STAT. ANN. § 2307.77. (Compl. at ¶ 11.) Plaintiff further alleges that "each of the defective conditions of the products as described above, pursuant to OHIO REV. CODE STAT. ANN. § 2307.73, was singularly a proximate cause of the harm for which plaintiff seeks to recover compensatory damages …" (Compl. at ¶ 12.) Finally, Plaintiff alleges that Defendants "were negligent in the design, manufacture, construction, assembly, production, modification, rebuilding, installation, testing, marketing, post-marketing, sale, servicing, and/or maintenance of the products and in failing to provide adequate warnings and instructions." (Compl. at ¶ 13.)

II. Procedural History

On September 6, 2022, Plaintiff initially filed suit against Medtronic and various healthcare Defendants in state court. (Cuyahoga County Court of Common Pleas, Case No. CV-22-968491.) On March 24, 2023, Defendants filed a motion to dismiss in the state court action. (*See* Doc. No. 7-2 at PageID #86.) On August 1, 2023, the state court denied Defendants' motion to dismiss as to all claims except for Plaintiff's claim for failure to warn, which was dismissed. (*Id.* at PageID #86–87.) On September 21, 2023, Plaintiff voluntarily dismissed the remaining claims against Medtronic. (*See* Cuyahoga County Court of Common Pleas, Case No. CV-22-968491, 9/21/2023 Docket Entry.)

On September 11, 2024, Plaintiff refiled her lawsuit in state court against Defendants by way of the present Complaint. (*See* Doc. No. 1-1 at PageID #7.) In her Complaint, Plaintiff asserted four

product liability claims under Ohio Rev. Code §§ 2307.74, 2307.75, 2307.76, and 2307.77 respectively.[3] (*See* Compl. at ¶ 11.) On October 1, 2024, Defendants removed this action from state court to federal court. (*See* Doc. No. 1.) Plaintiff did not file a motion to remand.

On October 10, 2024, Defendants filed their Motion to Dismiss for Failure to State a Claim. (Doc. No. 7.) On December 19, 2024, Plaintiff filed her Opposition to Defendants' Motion to Dismiss. (Doc. No. 9.) On January 2, 2025, Defendants filed their Reply in support of their Motion. (Doc. No. 10.) Accordingly, Defendants' Motion is ripe for a decision.

III. Standard of Review[4]

Defendants move to dismiss Plaintiff's claims as asserted against them under Rule 12(b)(6) of the Federal Rules of Civil Procedure. Pursuant to Rule 12(b)(6), the Court accepts Plaintiff's factual allegations as true and construes the Complaint in the light most favorable to Plaintiff. *See Gunasekera v. Irwin*, 551 F.3d 461, 466 (6th Cir. 2009). To survive a motion to dismiss under this Rule, "a complaint must contain (1) 'enough facts to state a claim to relief that is plausible,' (2) more than 'a formulaic recitation of a cause of action's elements,' and (3) allegations that suggest a 'right to relief above a speculative level.'" *Tackett v. M & G Polymers, USA, LLC*, 561 F.3d 478, 488 (6th Cir. 2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555–56 (2007)).

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[3] As indicated previously, Plaintiff also alleged that Defendants "were negligent in the design, manufacture, construction, assembly, production, modification, rebuilding, installation, testing, marketing, post-marketing, sale, servicing, and/or maintenance of the products and in failing to provide adequate warnings and instructions." (Compl. at ¶ 13.) The Court does not interpret this sole allegation as Plaintiff intending to assert a separate cause of action for negligence. However, to the extent that Plaintiff is attempting to assert a separate cause of action for common law negligence, that claim is dismissed because Plaintiff has failed to plead the necessary elements for asserting such a claim.

[4] The Court agrees with Defendants' assertion that the state court's denial of Defendants' previous motion to dismiss is not relevant here because the state court evaluated the motion under Ohio R. Civ. P. 8—a more lenient standard than the heightened federal pleading standard set forth in *Twombly*. *See Tuleta v. Med. Mut. Of Ohio*, 6 N.E.3d 106, 113–15 (8th Dist. 2014).

The measure of a Rule 12(b)(6) challenge—whether a complaint raises a right to relief above the speculative level—"does not 'require heightened fact pleading of specifics, but only enough facts to state a claim to relief that is plausible on its face.'" *Bassett v. Nat'l Collegiate Athletic Ass'n*, 528 F.3d 426, 430 (6th Cir. 2008) (quoting *Twombly*, 550 U.S. at 555–56). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). Deciding whether a complaint states a claim for relief that is plausible is a "context-specific task that requires the reviewing court to draw on its judicial experience and common sense." *Id.* at 679.

Consequently, examination of a complaint for a plausible claim for relief is undertaken in conjunction with the "well-established principle that Federal Rule of Civil Procedure 8(a)(2) requires only a short and plain statement of the claim showing that the pleader is entitled to relief. Specific facts are not necessary; the statement need only give the defendant fair notice of what the … claim is and the grounds upon which it rests." *Gunasekera*, 551 F.3d at 466 (quoting *Erickson v. Pardus*, 551 U.S. 89, 93 (2007)) (internal quotation marks omitted). Nonetheless, while "Rule 8 marks a notable and generous departure from the hyper-technical, code-pleading regime of a prior era, … it does not unlock the doors of discovery for a plaintiff armed with nothing more than conclusions." *Iqbal*, 556 U.S. at 679.

IV. Analysis

Plaintiff asserts four claims under the Ohio Product Liability Act ("OPLA") as follows: (1) Products Defective in Manufacture or Construction (O.R.C. § 2307.74); (2) Products Defective in Design or Formulation (O.R.C. §2307.75); (3) Products Defective Due to Inadequate Warning or Instruction (O.R.C. § 2307.76); and (4) Products Defective Due to Nonconformance with

Manufacturers' Representations (O.R.C. § 2307.77). Defendants challenge each of these claims on the premise that they fail to meet the pleading requirements of Federal Rule of Civil Procedure 8. Finally, Plaintiff alternatively seeks leave to conduct discovery to supplement her claim if this Court finds her allegations insufficient as pled. The Court will evaluate each claim below.

A. O.R.C. § 2307.74: Manufacturing Defect

The Court first begins with Plaintiff's manufacturing defect claim under § 2307.74.

In Defendants' Motion, Medtronic asserts that Plaintiff must establish that the device "deviated in a material way from the design specifications, formula, or performance standards of the manufacturer, or from otherwise identical units manufactured to the same design specifications, formula, or performance standards," and that the "defective aspect of the product was a proximate cause of the injury and that the defendant manufactured the actual product in question." (Doc. No. 7-1 at PageID #79.) Medtronic contends that "Plaintiff does not even pay lip service to these requirements in her Complaint" and instead simply alleges that "multiple ETTs 'failed' and that the products were defective." (*Id.*) Thus, Medtronic maintains that there are no "allegations setting forth the legal requirements of a manufacturing defect claim, much less *how* the ETTs supposedly failed to conform to specifications." (*Id.* (emphasis in original).) Finally, Medtronic asserts that Plaintiff is not entitled to an inference of deviation from any specification because all three ETTs experienced the same failure—as opposed to situations where only some products failed but others did not, implying that the former deviated from the product specifications established by the latter. (*Id.* at PageID #79–80.)

In her Opposition, Plaintiff asserts that she has sufficiently pled a claim under § 2307.74. (Doc. No. 9.) Specifically, Plaintiff points to her allegations that: (i) Decedent was a patient intubated

with Defendants' "Covidien" endotracheal tube; (ii) the "medical record of the procedure references clearly that the tube failed, allowing an air leak"; and (iii) "[f]urther attempts to intubate decedent with one or more Covidien tubes were unsuccessful as the tubes failed resulting in decedent's demise." (*Id.* at PageID #91.) Plaintiff indicates that her counsel previously attempted to secure product information from the Hospital but "received no cooperation and no product information" from the Hospital, which "thwarted/opposed discovery in the State case." (*Id.* at PageID #92.) Nonetheless, Plaintiff contends that the records attached to her Complaint are "crystal clear that the only device that failed was manufactured by Medtronic" and that the "product that failed was manufactured by [Defendants] and no one else." (*Id.* at PageID #93.) Although "at this time, [P]laintiff does not know why the device(s) failed," Plaintiff asserts that such failure(s) "clearly … resulted in [D]ecedent's demise," and thus, "Plaintiff should be permitted to conduct discovery to determine why [D]efendants' product failed." (*Id.*)

In Defendants' Reply, Medtronic contends that Plaintiff "cites no authority addressing similar allegations that would support her conclusion" that she has sufficiently pled her claims. (Doc. No. 10 at PageID #102–03.) Moreover, Medtronic asserts that Plaintiff "failed to address any of the case law cited in Medtronic's opening brief establishing that such barebones allegations are insufficient under *Twombly/Iqbal* to infer a cause of action as to product defect under Ohio law." (*Id.* at PageID #103.) Medtronic thus reiterates that Plaintiff's claims should be dismissed. (*Id.*)

Under the OPLA, a "product is defective in manufacture or construction if, when it left the control of its manufacturer, it deviated in a material way from the design specifications, formula, or performance standards of the manufacturer, or from otherwise identical units manufactured to the same design specifications, formula, or performance standards." *See* O.R.C. § 2307.74. For

manufacturing defect claims, "[a]t a minimum, courts have required allegations that the defendant manufactured the product, that the product was used by the plaintiff, that the product failed while being used by the plaintiff, and that the portion of the product that failed could be identified and is so identified in the complaint." *Barreca v. AngioDynamics, Inc.*, 2015 WL 5085260, at *3 (N.D. Ohio Aug. 27, 2015); *Grubbs v. Smith & Nephew, Inc.*, 2020 WL 5305542, at *4 (S.D. Ohio Sept. 4, 2020); *see also Fed. Ins. Co. v. Nanoscience Instruments, Inc.*, 2023 WL 2932282, at *2 (S.D. Ohio April 13, 2023). "At minimum, a plaintiff must provide a 'plausible basis to infer the device at issue materially deviated' from specifications or identical units." *Williams v. Boston Scientific Corp.*, 2023 WL 9596983, at *2 (N.D. Ohio Dec. 11, 2023) (citing *Parker v. Medtronic Sofamor Danek USA, Inc.*, 2021 WL 4751185, at *2 (N.D. Ohio Oct. 12, 2021)).

The Court finds that Plaintiff has sufficiently pled these elements at this stage. First, Plaintiff alleges that Defendants manufactured the ETT.[5] Second, Plaintiff alleges that the ETT was used in Decedent's treatment and failed during such use.[6] Third, Plaintiff alleges that the portion of the product that failed could be identified and is so identified. Specifically, Plaintiff pleads that the ETT experienced a failure at the "cuff"[7]—a specific part of the ETT.

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[5] *See* Compl. at ¶ 3 ("Based upon information and belief, said ETT was designed, manufactured and sold by the Medtronic defendants.").

[6] *See id.* ("[Decedent] was a patient at Western Reserve Hospital on and before September 12, 2020, and was being intubated with a Covidien endotracheal tube (ETT), which tube's cuff failed causing an air leak, improper ventilation and oxygen desaturation … Specifically, ETT No. 3 immediately experienced a catastrophic failure at the cuff …").

[7] *See id.* ("Specifically, ETT No. 3 immediately experienced a catastrophic failure *at the cuff* …") (emphasis added); *see also* Doc. No. 1-1 at PageID #15 ("The cuff was inflated and ventilation was attempted without success. ETT #3 immediately experienced a catastrophic failure at the cuff.").

These collective allegations provide a "plausible basis to infer the device at issue" materially deviated from "design specifications, formula, or performance standards of the manufacturer, or from otherwise identical units manufactured to the same design specifications, formula, or performance standards." *Williams*, 2023 WL 9596983, at *2; § 2307.74. Contrary to Defendants' assertions, Plaintiff does more than "merely allege[] that multiple ETTs 'failed' and that the products were defective …" (Doc. No. 7-1 at PageID #79.) Rather, Plaintiff *specifically* identifies the cuff as the source of the ETT's failure and describes such failure as "immediate[]" and "catastrophic." (Compl. at ¶ 3.) Such allegations create a plausible basis to infer that the ETT materially deviated from the performance standards of Defendants or from otherwise identical units manufactured.[8] *See, e.g.*, *Barreca*, 2015 WL 5085260, at *1–3 (finding allegation that "catheter had detached" from Mediport product with frayed ends sufficient to plead claim under § 2307.74 because the portion of the Mediport product that failed "could be identified and is so identified in the complaint").

Defendants' cited authority is distinguishable. First, Defendants assert that the court in *Perry v. Ethicon, Inc.*, 2022 WL 912214 (S.D. Ohio Mar. 29, 2022), dismissed a manufacturing defect claim related to a medical device "far more detailed than those alleged in Plaintiff's Complaint." (Doc. No. 7-1 at PageID #79.) In *Perry*, the plaintiff brought a manufacturing defect claim regarding a TVT-S device. 2022 WL 912214 at *11. There, however, the plaintiff alleged "that '[m]ost TVT-S pelvic mesh products are comprised' of the *same* 'biologically incompatible' polypropylene mesh." *Id.*

[8] Indeed, any assertion to the contrary would imply that "immediate[]" and "catastrophic" cuff failure is a performance standard set by Defendants for *all* their ETTs—in other words, that ETT #3 did not deviate from any performance standards for identical units because all units are designed to experience "immediate[]" and "catastrophic" cuff failure. To the extent that Defendants advance such a theory, the Court rejects it at this stage and instead finds a "'plausible basis to infer the device at issue materially deviated' from specifications or identical units." *Williams*, 2023 WL 9596983, at *2.

(emphasis added). In other words, the plaintiff expressly acknowledged that the allegedly deficient "pelvic mesh" at issue was used in *most* of the TVT-S products that were manufactured—the exact opposite of an allegation that one unit of a product deviated from the manufacturing specifications of otherwise identical units. *Id.* For this exact reason, the court dismissed the manufacturing defect claim. *Id.* at *12. Here, by contrast, Plaintiff specifically alleges that the particular ETTs used in Decedent's treatment suffered "immediate[]" and "catastrophic" failure specifically at the cuffs. (Compl. at ¶ 3.)

Defendants' reliance on *Tolliver v. Bristol-Myers Squibb Co.*, 2012 WL 3074538 (N.D. Ohio July 30, 2012), is misplaced. In *Tolliver*, the plaintiff was prescribed a prescription drug Plavix. *Id.* at *1. Some time later, the Food and Drug Administration issued a warning that Plavix could be less effective in certain people who could not metabolize the drug. *Id.* The plaintiff, however, alleged no allegations or facts showing that Plavix deviated from any design specifications or performance standards. *Id.* at *3. Nor did the complaint allege that the plaintiff was in the class of people for whom Plavix was less effective or that such lessened ineffectiveness resulted from a design deviation. *Id.* In fact, the plaintiff's complaint "contain[ed] no factual allegations at all to support a causal relationship between [the plaintiff's] taking of Plavix and his medical problems." *Id.* The only relevant allegation was a conclusory allegation that the defendants breached their duty to "manufacture Plavix in a safe a[nd] suitable manner for its intended purpose." *Id.* The present case is distinguishable. Plaintiff points to a specific defect (the "cuff") of particular ETTs used during Decedent's treatment. (*See* Compl. at ¶ 3; Doc. No. 1-1 at PageID #15.) Such "failure" was "immediate[]" and "catastrophic," implying that the ETTs at issue malfunctioned in a manner inconsistent with the performance standards for otherwise identical ETTs. (*Id.*) This is unlike the

plaintiff in *Tolliver*, who alleged no facts to support a plausible inference that the Plavix he took deviated from any other units of Plavix manufactured by the defendants. *See Tolliver*, 2012 WL 3074538, at *3.

Defendants' reliance on *O.M. Through McConnell v. KLS Martin LP*, 560 F. Supp.3d 1084 (N.D. Ohio 2021), also is misplaced. In *O.M.*, the plaintiff brought a manufacturing defect claim as to a medical device called a mandibular distractor. *Id.* at 1086. The plaintiff had two devices surgically implanted in his lower right and left jaw, and both devices failed within a short timeframe. *Id.* at 1086–87. A third mandibular distractor that was inserted in place of the broken device was not alleged to have failed. *Id.* at 1087. The court found that because the "third device inserted later did not fail and remained implanted longer than it took the first device to fail, the two devices originally inserted might plausibly have 'deviated in a material way … from otherwise identical units manufactured to the same design specifications, formula, or performance standards." *Id.* at 1088 (internal quotation marks omitted).

In *O.M.* the court expressly held that requiring a plaintiff to "explain *how* the subject devices deviated from Defendant's other mandibular distractors … seeks to hold [the plaintiffs] to a higher standard than the one Rule 8 imposes." *Id.* at 1088 (emphasis added). At this stage, Plaintiff merely needs to provide a "'plausible basis to infer the device at issue materially deviated' from specifications or identical units." *Williams*, 2023 WL 9596983, at *2. As explained above, Plaintiff has met this burden. Further, the plaintiff in *O.M.* did not plead any specific allegations as to the product failure other than noticing that "something was not right" with the devices and that "x-rays revealed the devices broke"—hence the court's heavy reliance on inferences. 560 F. Supp.3d at 1088. Yet in the instant matter, the "portion of the product that failed could be identified and is so identified

in the complaint"—the ETT's "cuff." *Barreca*, 2015 WL 5085260, at *3. Finally, nothing in *O.M.* suggests that Plaintiff's claim must fail simply because *all* the devices failed[9] as opposed to some failing and some succeeding. Just the opposite. The court in *O.M.* permitted an inference that the two devices that failed were—based on their failures—"manufactured at approximately the same time." *O.M.*, 560 F. Supp.3d at 1088. In similar fashion, it is entirely plausible for the failing ETT devices here to have also been "manufactured at approximately the same time" and thus *all* have suffered the same material deviations from the performance standards of the Defendants or otherwise identical units—namely, "immediate[]" and "catastrophic failure at the cuff." *Id.*; (Compl. at ¶ 3).

Accordingly, for all the reasons stated above, the Court finds that dismissal of Plaintiff's manufacturing defect claim under § 2307.74 is not warranted.

B. O.R.C. § 2307.75: Design Defect

The Court next turns to Plaintiff's design defect claim under § 2307.75.

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[9] In any event, contrary to Defendants' assertions, it is not entirely clear that Plaintiff would not be entitled to the *exact* same inference as in *O.M.* because the ETTs may have deviated with respect to their specific failures. Indeed, Exhibit B attached to Plaintiff's Complaint reveals that Decedent was first admitted to the Hospital on September 9, 2020. (Doc. No. 1-1 at PageID #15.) Specifically, Decedent was taken to the emergency department ("ED") via Emergency Medical Services ("EMS"), during which "squad found pulse ox to be 70%." (*Id.*) Then, "[i]n ED, he was put on a NRB with 100% O2, but continued to decline *resulting in emergency intubation*." (*Id.* (emphasis added).) After that emergency intubation, there is no mention of ETT failure until "[e]arly in the morning of 9/12/2020 [when] the patient's endotracheal tube (ETT) cuff failed" for the first time. (*Id.*) This failure prompted two further ETT replacements that morning, ETT #2 and ETT #3, each of which also failed. (*See id.*) It is presumed that all three ETT's referenced in these medical records are the same ETT's manufactured by Medtronic, given that Plaintiff's Complaint also references exactly three ETT's that were employed, and explicitly alleges that the initial ETT "was designed, manufactured and sold by the Medtronic defendants," and that "two more of defendants' ETT's were employed and failed." (Doc. No. 1-1 at PageID #9.) A liberal construction of this information—as required by Rule 8—suggests that Decedent was initially intubated with an ETT on September 9, 2020, and that no ETT failure occurred until September 12, 2024, three days later. Further, while the first ETT used for the initial intubation on September 9, 2020, appears to have been functional for three days, "ETT #3 immediately experienced a catastrophic failure at the cuff" upon being implemented. (Doc. No. 1-1 at PageID #15.) Under this alternative interpretation of Plaintiff's Complaint, the initial ETT remained in use "longer than it took" ETT #3 to fail—namely, three days without failure while ETT #3 failed immediately—thereby entitling Plaintiff to the inference that ETT #3 "might plausibly have deviated in a material way … from otherwise identical units manufactured to the same design specifications, formula, or performance standards." *O.M.*, 560 F. Supp.3d at 1088. Accordingly, in addition to the reasons discussed above, dismissal of Plaintiff's claim is premature at this stage when viewing her Complaint in the light most favorable to her as the non-moving party. *See Gunasekera*, 551 F.3d at 466.

In Defendants' Motion, Medtronic asserts similar arguments to the manufacturing defect claim discussed above. (Doc. No. 7-1 at PageID #80.) Specifically, Medtronic contends that while Plaintiff "concludes that there was a design defect in the ETT and that Medtronic was negligent in designing the product, these are not facts that adequately support a design defect claim." (*Id.*) Medtronic asserts that Plaintiff does not "recite the elements of a cause if action for design defect, or speak to the design of the ETT, its risks, or its benefits." (*Id.*) Finally, Medtronic again points to *O.M.* as having dismissed a "similarly deficient design defect claim." (*Id.*)

In her Opposition, Plaintiff reiterates the same arguments as initially described above in relation to her manufacturing defect claim. (Doc. No. 9 at PageID #91–94.) In Defendants' Reply, Medtronic reiterates that Plaintiff fails to address the case law cited in Defendants' Motion "establishing that such barebones allegations are insufficient under *Twombly/Iqbal* to infer a cause of action as to product defect under Ohio law." (Doc. No. 10 at PageID #102–03.)

Under the OPLA, a product is "defective in design or formulation if, at the time it left the control of its manufacturer, the foreseeable risks associated with its design or formulation … exceeded the benefits associated with that design or formulation." *See* O.R.C. § 2307.75(A). Some courts have found that to plead a design defect claim, the complaint must allege: "(1) the existence of a defect in the product at issue, (2) that the defect existed at the time the product left the hands of the manufacturer, and (3) the defect was the direct and proximate cause of the plaintiff's injury."[10] *Parker*, 2021 WL 4751185 at *3; *O.M.*, 560 F. Supp.3d at 1089; *see also Fox v. Kia America, Inc.*, 726 F. Supp.3d 765, 776 (N.D. Ohio 2024).

[10] At least one court in this district has determined that these elements "are the requirements a plaintiff must meet in order to survive summary judgment, not a motion to dismiss." *Williams v. Boston Scientific Corp.*, 2023 WL 9596983, at *2 (N.D. Ohio Dec. 11, 2023).

"As with manufacturing defect claims, design defect claims require that the complaint contain factual allegations as to which portions of the product failed." *Grubbs*, 2020 WL 5305542, at *5; *Fed. Ins. Co.*, 2023 WL 2932282, at *3; *see also Darwish v. Ethicon, Inc.*, 2020 WL 7129582, at *5 (N.D. Ohio Dec. 4, 2020) (citing cases). "Such facts elevate allegations beyond 'threadbare recitals or formulaic recitations of the elements of a claim." *Grubbs*, 2020 WL 5305542, at *5; *see also Marcum v. DePuy Orthopedics, Inc.*, 2013 WL 1867010, at *5 (S.D. Ohio May 2, 2013).

Just as with manufacturing defect claims, district courts have permitted design defect claims to survive dismissal where the complaint makes "allegations that the defendant manufactured the product; that the product was used by the plaintiff; that the product failed while being used by the plaintiff; and, that the portion of the product that failed could be identified and is so identified in the complaint." *Oblak v. Integra Lifesciences Corp.*, 2017 WL 1831098, at *2 (N.D. Ohio May 4, 2017) (citing cases); *Johnson v. Wal-Mart Stores East Inc.*, 2018 WL 1083269, at *4 (N.D. Ohio Feb. 28, 2018); *Thompson v. DePuy Orthopaedics, Inc.*, 2014 WL 2874268, at *5 (S.D. Ohio June 24, 2014). Notably, a "plaintiff is not required to set forth specific facts addressing the multi-factor balancing test set forth in Ohio Rev. Code § 2307.75 to survive a motion to dismiss." *Thompson*, 2014 WL 2874268, at *5; *Darwish*, 2020 WL 7129582, at *6 (finding that complaint did not need to "balance all of the risk/benefit factors contained in O.R.C. § 2307.75(B) and (C)").

In *Oblak*, the plaintiff brought manufacturing and design defect claims under the OPLA regarding certain medical hardware. 2017 WL 1831098, at *2–3. The plaintiff alleged that the medical hardware was manufactured and/or designed by one or more of the remaining named defendants, and that it failed after it was implanted during his reconstructive ankle surgery. *Id.* at *3. Further, the plaintiff alleged generally that one or more of the pieces of medical hardware, each of

which was expressly identified in the complaint, failed due to medical fatigue fracture. *Id.* The court concluded that this was sufficient to allege a design defect because the complaint alleged "that the defendant manufactured the product," "that the product was used by the plaintiff," "that the product failed while being used by the plaintiff," and "that the portion of the product that failed could be identified and is so identified in the complaint." *Id.* at *2. Notably, the court opined that "discovery will serve to clarify the exact nature and cause of the hardware failure, as well as which of the four remaining [d]efendants in this case … designed the specific piece or pieces of hardware that are alleged to have failed." *Id.* at *3.

The Court finds the present case to be analogous to *Oblak*. As discussed at-length above in relation to the manufacturing defect claim, Plaintiff alleges that Defendants manufactured the ETTs and that the ETTs were used in Decedent's treatment. (Compl. at ¶ 3; Doc. No. 1-1 at PageID #15.) Plaintiff further alleges the ETTs failed during such use. (*Id.*) Finally, and crucially, Plaintiff does not merely allege that the ETTs failed, but rather identifies the *specific* portion of the ETTs that failed—namely, that ETT #3 "immediately experienced a catastrophic failure *at the cuff*." (*Id.* (emphasis added).) Just as in *Oblak*, these allegations are sufficient to withstand dismissal at this early stage. 2017 WL 1831098, at *3; *see also Clark v. Wright Medical Technology, Inc.*, 2011 WL 2689381, at *2 (S.D. Ohio July 11, 2011) ("Plaintiffs have pled a plausible cause of action that satisfies *Twombley* [sic] and *Iqbal* because Plaintiffs alleged that the product broke either because it was defectively manufactured or defectively designed and have plead with specificity what portion of the product failed and when it failed.").

Defendants reference *O.M.* once more for the assertion that Plaintiff's Complaint is deficient. (Doc. No. 7-1 at PageID #80–81.) Again, however, the Court finds that the allegations in *O.M.* are

distinguishable from the present case. Specifically, the complaint in *O.M. solely* alleged the following: (1) that the plaintiff "noticed that 'something was not right' with the devices a few weeks after they were implanted"; (2) that "x-rays revealed the devices broke"; and (3) the devices "were defective in design and/or formulation pursuant to the provisions of O.R.C. Section 2307.75." 560 F. Supp.3d at 1088–89. Such allegations included *no* information identifying which *specific* portion of the devices failed. By contrast, the present Complaint specifically identifies the cuff of the ETTs as the point of failure. Accordingly, the Court finds *O.M.* to be distinguishable.

"[D]iscovery will serve to clarify the exact nature and cause of the … failure." *Oblak*, 2017 WL 1831098, at *3. At this preliminary stage, however, the Court finds that Plaintiff has met her burden in plausibly alleging a design defect sufficient to withstand dismissal.

C. O.R.C. § 2307.77: Failure to Conform to Representations

The Court next turns to Plaintiff's failure to conform to representations claim under § 2307.77.

In Defendants' Motion, Medtronic contends that Plaintiff does not state a viable failure to conform claim in her Complaint. (Doc. No. 7-1 at PageID #81.) Specifically, Medtronic asserts that a claim under § 2307.77 requires a product not conforming to a "representation made by [the] manufacturer," and maintains that "Plaintiff does not allege a single representation made by [Defendants]." *Id.* Thus, Medtronic submits that Plaintiff fails to meet Rule 8 pleading requirements. *Id.*

In Plaintiff's Opposition, Plaintiff simply reiterates that her Complaint sufficiently alleges her claims. (Doc. No. 9.) Plaintiff does not specifically address her failure to conform claim under § 2307.77. (*Id.*) In Defendants' Reply, Medtronic reiterates that Plaintiff fails to address the case law cited in Defendants' Motion "establishing that such barebones allegations are insufficient under

Twombly/Iqbal to infer a cause of action as to product defect under Ohio law." (Doc. No. 10 at PageID #102–03.)

Under the OPLA, a "product is defective if it did not conform, when it left the control of its manufacturer, to a representation made by that manufacturer." *See* O.R.C. § 2307.77. The OPLA defines a "representation" as "an express representation of a material fact concerning the character, quality or safety of a product." O.R.C. § 2307.71(A)(14). To succeed on a failure to conform claim, a plaintiff must show that: "(1) the manufacturer made a representation as to a material fact relating to the character or quality of the product; (2) the product did not conform to that representation; (3) the plaintiffs justifiably relied on that representation; and (4) the plaintiffs' reliance on the representation was the direct and proximate cause of the plaintiffs' injuries." *Tolliver*, 2012 WL 3074538, at *5; *see also O.M.*, 560 F. Supp.3d at 1090–91; *Tomlin v. Smith & Nephew, Inc.*, 2020 WL 5230830, at *2–3 (S.D. Ohio Sept. 2, 2020).

Here, Plaintiff fails to even allege a single representation made by Defendants. Her Complaint "identifies no representation to which the device did not conform." *O.M.*, 560 F. Supp.3d at 1091. Nor does Plaintiff make any attempt in her Opposition to address this claim. Rather, the only allegation relevant to this claim in Plaintiff's Complaint is the conclusory allegation that the ETTs "were defective because they did not conform to representations made by their manufacturers as described in OHIO REV. CODE STAT. ANN. § 2307.77." (Compl. at ¶ 11.) Such an allegation fails to state a claim under the Rule 8 standard. *See O.M.*, 560 F. Supp.3d at 1091.

Accordingly, the Court hereby dismisses Plaintiff's claim under § 2307.77.

D. O.R.C. § 2307.76: Inadequate Warning or Instruction

Next, the Court turns to Plaintiff's inadequate warning or instruction claim under § 2307.76.

In Defendants' Motion, Medtronic first asserts that Plaintiff's claim under § 2307.76 is barred under the doctrine of claim preclusion because the state court already dismissed the claim. (Doc. No. 7-1 at PageID #81–82.) Medtronic then contends that even if this Court were to independently decide the issue, Plaintiff does not state a viable claim because Plaintiff makes no attempt to allege a "duty to warn against reasonably foreseeable risks, breach of that duty, and an injury proximately caused by said breach." (*Id.* at PageID #82.)

In Plaintiff's Opposition, Plaintiff simply reiterates that her Complaint sufficiently alleges her claims. (Doc. No. 9.) Plaintiff does not specifically address the merits of her claim under § 2307.76. (*Id.*) Notably, however, Plaintiff acknowledges that this claim was dismissed by the state court on August 1, 2023. (*Id.* at PageID #94.) In Defendants' Reply, Medtronic reiterates that Plaintiff fails to address the case law cited in Defendants' Motion "establishing that such barebones allegations are insufficient under *Twombly/Iqbal* to infer a cause of action as to product defect under Ohio law." (Doc. No. 10 at PageID #102–03.)

Under the OPLA, a "product can be defective due to an inadequate warning or instruction either at the time of marketing, when it left the control of its manufacturer, or at post-marketing." *See* O.R.C. § 2307.76(A)–(B); *O.M.*, 560 F. Supp.3d at 1090. A claim for inadequate warning or instruction under § 2307.76 has three elements: "(1) a duty to warn against reasonably foreseeable risks; (2) breach of this duty; and (3) an injury that is proximately caused by the breach." *O.M.*, 560 F. Supp.3d at 1090 (citing cases).

The Court finds that dismissal of Plaintiff's claim under § 2307.76 is warranted. First, Plaintiff's claim is independently barred on the basis that it has already been dismissed by the state court, as acknowledged by Plaintiff. (Doc. No. 9 at PageID #94.) Second, notwithstanding the prior

dismissal, Plaintiff fails to set forth any allegations that Defendants had a duty to warn against reasonably foreseeable risks, or that Defendants breached this duty by failing to warn of some reasonably foreseeable risk. *See O.M.*, 560 F. Supp.3d at 1090. Once again, Plaintiff simply reiterates a conclusory statement that "the products as manufactured by [D]efendants … were defective due to inadequate warnings and instructions as described in OHIO REV. CODE STAT. ANN. § 2307.76." (Compl. at ¶ 11.) This sole allegation again fails Rule 8 pleading requirements.

Accordingly, the Court hereby dismisses Plaintiff's claim under § 2307.76.

E. Plaintiff's Request for Discovery

Finally, the Court turns to Plaintiff's request for leave of court to conduct discovery.

In her Opposition, Plaintiff "seeks leave of court to conduct discovery to plead with greater specificity, should the Court order that same is necessary." (Doc. No. 9 at PageID #93.) Plaintiff indicates that prior to filing the initial suit in state court, she requested extensive product information from the Hospital and asked for the intubation devices to be preserved, to which she "received no cooperation and no product information." (*Id.* at PageID #92.) Plaintiff further notes that Defendants are aware of Plaintiff's dilemma because "counsel for [P]laintiff and counsel for [Defendants] had a lengthy telephone conversation," followed by Plaintiff's counsel "immediately thereafter forward[ing] to counsel for Medtronic all medical records in [P]laintiff's possession that made reference to the product or products in question." (*Id.*) Based on these occurrences, Plaintiff requests discovery to "enable her to determine the cause of the reported intubation devices failures" and "to plead with greater specificity." (*Id.* at PageID #92–93.)

In Defendants' Reply, Medtronic contends that binding Sixth Circuit precedent that "*Twombly* and *Iqbal* do not permit a plaintiff to proceed past the pleading stage and take discovery in order to

cure a defect in a complaint." (Doc. No. 10 at PageID #103.) Accordingly, Medtronic asserts that Plaintiff should not be permitted leave to conduct discovery. (*Id.* at PageID #104.)

It is well-settled that "[t]he Supreme Court's decisions in *Twombly* and *Iqbal* do not permit a plaintiff to proceed past the pleading stage and take discovery in order to cure a defect in a complaint." *Patterson v. Novartis Pharmaceuticals Corp.*, 451 Fed. App'x 495, 498 (6th Cir. 2011); *see also Shepard and Associates, Inc. v. Lokring Technology, LLC*, 2022 WL 2398392, at n.4 (N.D. Ohio July 1, 2022) ("A plaintiff is not entitled to conduct discovery and gather facts necessary to cure defects in a pleading."). Indeed, district courts addressing OPLA claims have rejected this exact argument that a plaintiff "cannot plead more than they did without access to information 'not readily available publicly [that] will have to be obtained through discovery,'" finding that Rule 8 "does not unlock the doors of discovery for a plaintiff armed with nothing more than conclusions." *O.M.*, 560 F. Supp.3d at 1090. Thus, Plaintiff is not entitled to discovery to cure the defects in her now-dismissed claims.

Accordingly, Plaintiff's request for leave of court to conduct discovery is denied.

V. Conclusion

For the reasons set forth above, the Court **GRANTS IN PART and DENIES IN PART** Defendants' Motion to Dismiss. The Court **GRANTS** Defendants' Motion as to Plaintiff's claims under § 2307.76 and § 2307.77. The Court **DENIES** Defendants' Motion as to Plaintiff's claims under § 2307.74 and § 2307.75.

IT IS SO ORDERED.

s/Pamela A. Barker
PAMELA A. BARKER
U. S. DISTRICT JUDGE

Date: April 24, 2025